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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,704	09/30/2004	Sean P. Selover	101896-0283	5703

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NUTTER MCCLENNEN & FISH LLP
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EXAMINER

SWIGER III, JAMES L

ART UNIT	PAPER NUMBER
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3775

NOTIFICATION DATE	DELIVERY MODE
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09/18/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/711,704	Applicant(s) SELOVER ET AL.	
	Examiner JAMES L. SWIGER	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14-17 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14-17 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/18/2009; 6/1/2009; 5/29/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The continuing date at the beginning of the specification should be updated to reflect the current status of each application. Case 10/738130 is now a US Patent.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 16, 24, 28, 32, 36, 40 of U.S. Patent No. 7527638 in view of Moskovitz (US Patent 5,741,261). Patent '638 discloses the claimed method including the steps of placing a spinal screw in a pathway, advancing a spinal screw that is mated to a percutaneous access device towards the vertebra, and also placing a spinal fixation rod lengthwise and in an orientation substantially parallel to a longitudinal axis of the pathway. US Pat '638 discloses the claimed invention except for

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the steps of forming an incision through tissue, identifying a muscle plane and then using a tool to create a space between a muscle plane. Moskovitz et al. disclose a minimally invasive surgical method comprising the steps of forming an incision through tissue (see incision in skin, Fig. 2) that is located adjacent a vertebra (V), identifying a muscle plane between muscles (Col. 8, lines 1-45; note: as the skin is retracted and the subcutaneous fat dissected, a surgeon would be able to see the fascia), and inserting a blunt tip (such as Figs. 14 or 25), along a muscle plane between the incision and the vertebra. See Col. 7, lines 1-55). It is noted that Moskovitz et al. teaches that the present invention and method provides for a minimally invasive procedure as it utilizes existing, natural muscle planes between muscles to access the spine and cause minimal tissue damage and trauma in performing the procedure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Anderson having the steps of accessing the spine in a minimally invasive way so that there is minimal trauma to the spine when performing spinal surgery.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 14-17 and 25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "the first anchor" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews (US patent 5,357,983) in view of Teitelbaum (US Publication 2002/0082598). Matthews discloses a minimally invasive surgical method comprising the steps of making a first incision in a patient (incision shown as 27, Fig. 1) and inserting a blunt tip of a tool (Figs. 4a-4c) through the incision and manipulating the tip to extend through a muscle plane to create a first site on a vertebral body. As shown in Fig. 1, a bone screw or fixation member is in the muscle plane area which extends down from #27). The tools used to introduce a fixation member are considered atraumatic (Col. 8, lines 60-65). It is also noted that Mathews refers to the "suprafaciscal subcutaneous space (25, see also Col. 7, lines 60-65) which defines the area that creates a muscle plane between two muscles. Mathews also teaches use of a guidewire to target the surgical location on a vertebrae through a tool, where the tool is then removed and a cannulated screw, or first implant, which would fit over a guidewire is inserted along the guidewire adjacent the first vertebral site. This procedure can be repeated in a second location as well.

Mathews discloses the claimed method except for the step of placing a fixation element through a pathway to then couple to the end of a bone anchor, or an additional step where a fixation anchor could attach to a second anchor. Teitelbaum discloses a system designed for a percutaneous procedure that also has an implant guided to a surgical site via a guidewire. Teitelbaum also discloses the step of placing a fixation element, such as a rod (222) in a substantially parallel orientation (at least the two orientations in Figs. 12 and 18 are considered substantially parallel to one another), where the fixation element connect to a first implant (see location near 216, Fig. 16), and where this procedure also permits the fixation element to connect to a second implant as well. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Mathews having the step of inserting a spinal fixation screw with a guide wire and placing a fixation element such as a rod in view of Teitelbaum in order to perform a minimally invasive surgical method and secure vertebrae.

Allowable Subject Matter

Claim 25 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant amendment submitted in the response filed 5/29/2009 have been fully considered and are persuasive. However, after further consideration, additional

considerations and rejection were found based on the prior art. Rejections and remaining pending issues are found above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on M-F 9-530.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L. SWIGER/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775